California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
PETE WILSON, GOVERNOR

DEPARTMENT OF CONSUMER AFFAIRS
BOARD OF PHARMACY
NORTHERN COMPLIANCE COMMITTEE
MINUTES

DATE: February 3, 1999

TIME: 10:00 a.m. – 11:32 a.m.

LOCATION: Department of Consumer Affairs
Director's Conference Room
400 R Street, Suite 3020
Sacramento CA 95814

BOARD MEMBERS PRESENT:
Thomas Nelson, Chairperson
Richard Mazzoni, Board Member
Robert Elsner, Board Member

STAFF PRESENT:
Robert Ratcliff, Supervising Inspector
William Wislosky, Pharmacy Inspector
Linda Kapovich, Enforcement Technician

ALSO PRESENT:
Robert E. Luna, NR Owner
Robert Seiwert, RPH, PIC
Patricia Ann Nero, RPH, PIC
Lola Thompson, Deputy Director
Wai-Leng Wu, RPH
Gonzalo Avila, RPH, PIC
Steven Gray, Pharmacy Professional Affairs
Matilda Tam. Pharmacy Services Director
Divina Berenguer, RPH
Debra Ann Coronado, RPH, PIC
Brett Stark, District Pharmacy Supervisor

CALL TO ORDER

Chairperson Thomas Nelson called the meeting of the Northern Compliance Committee to order at 10:02 a.m.

A. DISCIPLINARY APPEARANCES

1. Raymond P. Belchar, RPH 21230 CI 95 13226
Robert Seiwert, RPH 37392, Former PIC
Robert Luna, NR Owner

Value Pharmacy, PHY 39260
1600 Creekside, Suite 1700
Folsom, CA 95630

Robert Seiwert and Robert Luna appeared before the Northern Compliance Committee as a result of an investigational audit for the time period of 10/4/96 to 2/5/97, which revealed that shortages for three controlled substances. The pharmacy used the three controlled substances in prescription compounding. The three substances were: Phentermine 30mg, short 4,802 capsules; Fenfluramine powder, short 75 Grams; Hydrocodone powder, short 15 Grams. Additionally, PIC Seiwert dispensed numerous Hydrocodone plus nonnarcotic prescriptions, which contained in excess of 15mg of Hydrocodone, without triplicate prescriptions as required by law.

On April 30, 1997 a violation notice was issued to Value Pharmacy, Robert Seiwert, and Robert Luna for violation of:

- Health and Safety Code section 11164 (a) – Record of practitioner dispensing schedule II controlled substance.

- Health and Safety Code section 11056-(3) (4) – Schedule III controlled substances chlorphentermine, and clortermine.

On May 5, 1998 a violation notice was issued to Value Pharmacy, Robert Seiwert, Robert Luna, and Raymond Belchar for violation of:

- Business and Professions Code section 4333 – Maintaining prescriptions. Other drug records on premises open to inspection; Waiver; Willful failure to keep or permit inspection of records of prescriptions, Other records as misdemeanor.

- Business and Professions Code section 4301 (n) – Unprofessional conduct.

- Business and Professions Code section 4113 (a) – Pharmacist in charge: Notification to board; Responsibilities.

Robert Luna reported to the committee that Raymond Belchar is now deceased.

RPH Seiwert stated that he never denied any board inspector access to licensed area.

The committee questioned RPH Seiwert with regard as to why he signed an inspection report dated December 31 1996, in which it states inspection declined.

The committee questioned RPH Seiwert as to why he refused to sign an official receipt on December 31, 1996.

RPH Seiwert responded that he declined to sign the original receipt because he was not present at the time of the board inspectors first two visits to the pharmacy, when the records were removed.

The committee explained to RPH Seiwert that the board inspector took controlled substance inventories, and a blue binder for compounding formulas on the day that RPH Seiwert declined to sign the receipt.

The committee asked RPH Seiwert to continue his explanation of his understanding as to the findings in this investigation.

RPH Seiwert explained that the pharmacy was in a medical building, he had a verbal protocol set up with the physicians in the building to compound phentermine and fenfluramine in "one a day" dosage form.

The committee admonished RPH Seiwert that a protocol is a written agreement signed by the dispensing physician. The committee explained that what RPH Seiwert is describing is a verbal agreement, not a protocol. The committee further explained to RPH Seiwert that if he had obtained a written protocol from the prescribing physicians he may not have been in violation of the law.

RPH Seiwert responded that it was his intent to comply with the record keeping laws by re-writing the prescriptions.

The committee asked RPH Seiwert if he was re-writing all of the phentermine fenfluramine presciptions, how would he be able to ascertain if the physician wanted to prescribe the more common commercially available products.

RPH Seiwert responded that if there were any question the physician would have been contacted.

The committee asked RPH Seiwert to explain the excessive dosage of hydrocodone.

RPH Seiwert responded that it was his understanding that the dosage would qualify the hydrocodone as a schedule III. RPH Seiwert was issued a violation notice for this violation. At that time RPH Seiwert reduced his compound to be in compliance.

The committee asked RPH Seiwert if he is now employed in a compounding pharmacy.

RPH Seiwert responded that he is the PIC and Owner of Sierra Pharmacy. RPH Seiwert added that he now specializes in pain management.

The committee questioned Mr. Luna if he now or in the future planned to own another pharmacy?

Mr. Luna responded that he does not now own a pharmacy, and he does not plan to own one in the future.

The committee stated that they want the change of PIC form and discontinuance of business forms completed before RPH Seiwert and Mr. Luna leave the meeting today.

Mr. Luna stated that he would be happy to comply.

M/S/C: Nelson / Mazzoni

The committee accepts the appearance of Robert Seiwert, Robert Luna, and Value Pharmacy; (a) The matter is to be made a part of the record of Robert Seiwert, RPH 37392, and Value Pharmacy, PHY 39260. No further action will be taken at this time.

2. Patricia Ann Nero, RPH 26506, PIC CI 97 15633

San Mateo County General Hospital Pharmacy
222 39th Avenue
San Mateo, CA 94403
HPE 19576

Lola Thompson, Deputy Director San Mateo County General Hospital

Patricia Ann Nero appeared before the Northern Compliance Committee as the result of an investigation that revealed that North County Health Center Pharmacy operated without a pharmacist on duty from March 30, 1998 until April 17, 1998.

The hospital management made a decision to depot prescription medications in its pharmacy. The prescriptions were tendered at the county hospital, and retrieved by a technician daily. The technician provided the patients with the prescription medications. When consultation was required, a nurse or physician on duty performed it.

On July 28, 1998 a violation notice was issued to North County Health Care Center Pharmacy for violation of:

- California Code of Regulations section 1717 (e) – No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

On August 24, 1998 a violation notice was issued to North County Health Care Center Pharmacy for violation of:

- California Code of Regulations section 1707.2 – Duty to consult.

RPH Nero stated that she had no notice that the former pharmacist-in-charge was leaving. The pharmacy was short staffed due to the fact that one pharmacist was out on maternity leave, and another pharmacist had just retired. When the former pharmacist-in-charge walked out, the pharmacy was missing three pharmacists. At the time of the incident the county had no outside contracts, and it takes approximately four weeks to set them up.

The committee asked RPH Nero if the county has outside vendors to serve their patients?

RPH Nero responded that they do now, but at the time of the incident they did not.

The committee admonished RPH Nero for leaving a technician alone in a licensed area, and stated that this is a serious violation. The technician, no matter how responsible she was, is not licensed for and should not be held responsible for such accountability.

RPH Nero responded that in retrospect this arrangement was an error in judgement.

The committee asked RPH Nero if she has a precautionary measures in place to prevent a similar situation in the future?

RPH Nero responded that their staffing levels are back up to standard now, and the county has outside contracts in place. In addition the county now has a pharmacy benefit management program in place so that county patients can go to any pharmacy and the county will pay for it.

M/S/C: Mazzoni / Nelson

The committee accepts the appearance of Patricia Ann Nero and San Mateo County General Hospital Pharmacy; (a) The matter is to be made a part of the record of Patricia Ann Nero, RPH 26506, and San Mateo County General Hospital Pharmacy, HPE 19576. (b) Patricia Ann Nero, RPH 26506 is to be cited and fined $500. for failure to provide patient consultation as required (c) San Mateo County General Hospital Pharmacy, HPE 19576 is to be cited and fined $1,000. for failure to provide patient consultation as required. No further action will be taken at this time.

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3. Gonzalo Avila, RPH 24994, PIC CI 97 14806
Wai Leng Wu, RPH 46891

Kaiser Foundation Health Plan Pharmacy
Milpitas, CA 95035
PHY 30252

Mr. Cliff Wong, Director of Pharmacy Operations Kaiser
Ms. Matilda Tam

Gonzalo Avila and Wai Leng Wu appeared before the Northern Compliance Committee as the result of an investigation that revealed that on July 27, 1997, RPH Wu dispensed Verapamil 180mg. SR (Sustained Release), on a refill prescription for Verapamil 80mg.

On March 20, 1998, a violation notice was issued to Kaiser Foundation Health Plan Pharmacy and Wai Leng Wu for violation of:

- California Code of Regulations section 1716 – Variation from prescription.
- Business and Professions Code section 4301 (n) – Unprofessional Conduct as it relates to the dispensing error.

The committee asked those present to explain the staffing on the day of the incident.

RPH Wu explained that she and a technician were working on that day; both of them had a one-hour lunch. The incident happened right after lunch, when the pharmacy was very busy.

The committee asked what steps the pharmacy has taken to prevent future incidents.

RPH Avila responded that the pharmacy now stocks different brands for each of the strengths of Verapamil. The pharmacy has also moved the stock so that the 80 mg and the 180 mg are not stocked next to each other.

The committee questioned those present as to how the pharmacy handles incidents internally, and how their quality assurance takes place. What are the policies and procedures in these matters?

RPH Avila explained that the pharmacist completes an internal form, and then shares the information with all of the staff pharmacists. All errors that do not leave the control of the pharmacy staff are controlled at the pharmacy management level. If the error leaves the control of the pharmacy staff, even if the medication is only handed to the patient, but never leaves the pharmacy. Then corporate management handles the error. At no time does Kaiser report the errors to any outside agency.

M/S/C: Nelson / Mazzoni

The committee accepts the appearance of Gonzalo Avila, Wai Leng Wu, and Kaiser Foundation Health Plan Pharmacy; (a) The matter is to be made a part of the record of Wai Leng Wu, RPH 46891, and Kaiser Foundation Health Plan Pharmacy, PHY 30252. No further action will be taken at this time.

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4. Debra Ann Coronado, RPH 48381, PIC — CI 97 15079
Divina Berenguer, RPH 36266, Former PIC

Walgreens
Los Gatos, CA 95030
PHY 30749

Brett Stark, District Pharmacy Supervisor Walgreens Corp.

Debra Ann Coronado and Divina Berenguer appeared before the Northern Compliance Committee as the result of an investigation that revealed that on November 11, 1997, Berenguer dispensed Prevacid 15mg. on a prescription written for Prevacid 30mg.

On March 26, 1998 a violation notice was issued to Walgreens and Divina Berenguer for violation of:

- California Code of Regulations section 1716 – Variation from prescription.

- California Code of Regulations section 1707.2 – Duty to consult.

The committee asked RPH Berenguer if she was the dispensing pharmacist; and to explain the pharmacy's process for filing a new prescription.

RPH Berenguer responded that she does not remember filling it, but her initials are on the prescription. RPH Berenguer explained the pharmacy's process for filing a prescription. The technician takes in the presciptions, verifies the patient information, and types the labels. The pharmacist fills the prescription. The pharmacist then dispenses the medication to the patient, and provides consultation. If the patient is not present, the technician files the medication in the "will call" bins.

The committee asked RPH Berenguer at what point does the pharmacist review the patient's profile?

RPH Berenguer explained that the computer flags all drug interactions, and duplicate therapies.

The committee suggested to RPH Berenguer that pharmacist's skills would be better utilized by inputting the patient information in the computer system and reviewing the patient profiles.

The committee asked those present once the prescription is placed in the "will call" bins, how can the clerk know that it is a new prescription?

RPH Berenguer responded that the word "NEW" is printed on the prescription receipt.

The committee asked RPH Berenguer how does the pharmacy document when a patient refuses consultation?

Mr. Stark responded that they have no policy in place to document when a patient refuses consultation.

The committee suggested that it is good business practice to document when a patient refuses consultation.

The committee admonished those present that it seems as if things are not clear to all of them as to how things are handled in the pharmacy.

Mr. Stark responded that RPH Berenguer is no longer employed at that location.

The committee pointed out that the original prescription clearly states 30 mg. had the pharmacist checked the label against the original prescription document the error could have been caught prior to it being dispensed to the patient.

The committee questioned RPH Coronado with regards to pharmacy staffing on the day of the violation.

RPH Coronado responded that she could not remember what the staffing was for each shift on the day the incident occurred. The pharmacy was well staffed, but the staff was just becoming familiar with the new computer system.

RPH Coronado added that they have made many changes since this violation occurred. The verification process has been changed to more of an assembly line procedure. Now three or four people see the prescription before it is dispensed which gives the pharmacy a much better chance to catch errors.

The committee asked RPH Coronado how many people review the patient profile before the medication is dispensed.

RPH Coronado explained that the pharmacy keeps a pharmacist at the verification computer. Each medication has it's own bar code. The pharmacist scans the bar code, and any drug interaction will automatically generate a warning. The pharmacist can also review the patient profile at that time for any other reason as well.

The committee asked RPH Coronado is she realized that patient profile review is part of patient consultation, and required by law?

RPH Coronado responded that she is aware of that.

The committee admonished those present that they need to be intimately involved in patient profile review, not rely on the computing machine to catch everything.

M/S/C: Nelson / Mazzoni

The committee accepts the appearance of Divina Berenguer, Debra Ann Coronado, and Walgreens; (a) The matter is to be made a part of the record of Divina Berenguer, RPH 36266, and Walgreens, PHY 30749. No further action will be taken at this time.

There being no additional discussion, the meeting was adjourned at 11:32 a.m.